

REMARKS/ARGUMENTS

Claims 57 and 59-63 are pending in this patent application. All pending claims currently stand rejected. In this response, no claims are amended, no new claims are added, and no claims are canceled. Thus, the Applicants respectfully submit that no new matter has been included in this response.

The Examiner has stated that the following are known in the art:

- a) the use of policosanols in lowering plasma cholesterol levels; and
- b) the use of combination therapy in the medical art.

Solely to avoid being estopped from addressing these issues in the future, the Applicants respectfully request that the Examiner point to specific reference teachings or knowledge in the art supporting these statements.

Response to Rejection of Claims 57 and 59-63 under 35 U.S.C. §103

- A. **The rejection of claims 56-63 under 35 U.S.C. §103 based on the combination of EP 952208, US5952393, US6596776, US4495094, US6394230 and the Jones et al. reference is improper because there is no evidence in the references that particular combinations of components would have an improved effect greater than the sums of the individual effects of the components.**

Applicants have reviewed the disclosure of the cited references and respectfully disagree that the disclosures therein destroy the patentability of the claims. Our detailed reasons follow.

A *prima facie* case of obviousness requires that the references or combination thereof disclose each and every element of the claim. Where a claimed feature is not taught there must be some reason, in the art or otherwise and articulated by the Examiner, to modify the reference teachings to arrive at the claimed invention. Applicants note that the recent decision in *KSR Int'l Co. v. Teleflex Inc.* (127 S. Ct. 1727, 1734 (U.S. 2007)) is not pertinent to the present application because the claimed invention is not a combination of previously known elements and is not in a predictable art area. Under prior Supreme Court and the Federal Circuit decisions, the obviousness or nonobviousness of subject matter claimed is determined against the background of the following three factual inquiries:

- (1) *The scope and the content of the prior art;*
- (2) *The differences between the prior art and the claims at issue; and*
- (3) *The level of ordinary skill in the pertinent art.*

Graham v. John Deere Co., 383 U.S. 1 (U.S. 1966). In view of these parameters for determining obviousness, the claimed invention is not obvious, at least without a significant dose of hindsight.

1. Content of the Prior Art – none of the prior art references disclose the claimed ranges of policosanol.

The Applicants have previously discussed in detail the shortcomings of the references relied on by the Examiner. In summary, each of these references fails to teach the claimed composition, most particularly with respect to the very much larger concentrations of tertacosanol and docosanol. Specifically, none of the references discloses that compositions having from 20-60% docosanol will be effective in lowering cholesterol.

The Examiner's reliance on *In re Russell* (439 F.2d 1228 (CCPA 1971)) and the criticality of ranges is misplaced. *In re Russell* relates to the situation where a reference discloses a range that is either broader than or overlaps with the claims of the pending application. It is true that where a single reference discloses a range that is generic to the claimed range, criticality must be shown for a range within the previously disclosed, broad range. *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) (determining where in a **disclosed** set of percentage ranges the optimum combination of percentages lies is *prima facie obvious*") (emphasis added). In the present case, however, the claimed ranges are not generically disclosed and do not overlap with the ranges disclosed in the art. Thus, the rationale used in *In re Russell* cannot support the Examiner's rejection.

2. The differences from the prior art – none of the prior art references discloses the claimed composition.

None of the cited references discloses ranges broader than or overlapping with each of the claimed compositional features. The Examiner has, instead, pieced together features from the several references in order to meet the claim limitations. The picking and choosing of limitations from different references is a hallmark of a determination of obviousness based on the improper use of hindsight. *KSR Int'l Co.* 127 S. Ct. at 1741 ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.")

In the present case, there is simply no indication in the cited art that, for example, compositions having 300% to 1100% more docosanol content will be useful. And because the combination of prior art compositions is inherently a dilutive action, no combination of prior art compositions having lower docosanol content can result in a composition with such a high level of docosanol. Moreover, the present invention is fundamentally related to the interplay of chemistry – an unpredictable art – and biology – another unpredictable art. Thus, to the extent the *KRS* decision allows an “obvious to try” approach, that decision is limited to predictable art areas and is inappropriate in the present case. *Id.* at 1742. (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, *predictable* solutions, a person of ordinary skill has good reason to pursue the *known* options within his or her technical grasp.”) (emphasis added). It has long been held that in chemical cases, obvious to try or obvious to experiment is an inappropriate standard and the *KSR* decision being strictly limited to the facts therein (“What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.” *Id.*) has done nothing to change this. *See, e.g., In re Dow Chemical Co.*, 837 F.2d 469; *In re O'Farrell*, 853 F.2d 594.

Consequently, the Applicants respectfully submit that each of these *Graham* factors indicate the rejection is improperly based on both misapplied legal precedent and hindsight-based picking and choosing of the individual claim elements from a variety of art references. Therefore, the rejection is improper and should be withdrawn.

CONCLUSION

Applicants have addressed all of the Examiner’s rejections. Applicants believe that the claims are now in condition for allowance and respectfully request that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicants’ attorney, the Examiner is invited to contact the attorney at the number noted below. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-3420, reference 22106965-105181 (Friedrich).

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Respectfully submitted,

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